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September 10, 2002

IDS # 9  
PATENT APPLICATION  
DOCKET NO.: 0975 1005 806  
10/29/02  
1642

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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SEP 16 2002

TECH CENTER 1600/2900

Applicants: Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel

Application No.: 09/756,398 Group Art Unit: 1642

Filed: January 8, 2001 Examiner: Karen Canella

Title: ANTI-TNF ANTIBODIES AND PEPTIDES OF HUMAN TUMOR NECROSIS FACTOR

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, P.O. Box 2327, Arlington, VA 22202

on 9-10-02 Date Signature Linda M. Amato

Linda M. Amato  
Typed or printed name of person signing certificate

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
P.O. Box 2327  
Arlington, VA 22202 20231 20231

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)
- ☐ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☒ under 37 CFR 1.97(c) together with either:
  - ☐ a Statement under 37 CFR 1.97(e), as checked below, or
  - ☒ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
  - ☐ a Statement under 37 CFR 1.97(e), as checked below, and
  - ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)

09/16/2002 AOSHAWI 00000010 09756398 180.00 0P  
01 FC:126

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

- ☒ Enclosed herewith is form PTO-1449:

☒ Copies of the cited references are enclosed.

- ☐ Copies of cited references are enclosed except those entered in prior applications, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. The earlier applications contains copies of the cited references.

- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.

- ☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:

- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ the enclosed English language abstract.

- ☒ Applicant requests that the following pending applications be considered:

Examiner's  
Initials

\_\_\_\_ U.S. Patent Application No.10/176,460, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed June 20, 2002, Docket No.: 0975.1005-019

\_\_\_\_ U.S. Patent Application No. 10/187,121, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed June 28, 2002, Docket No.: 0975.1005-020

\_\_\_\_ U.S. Patent Application No. 10/186,559, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed June 28, 2002, Docket No.: 0975.1005-021

U.S. Patent Application No. 10/198,845, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed July 18, 2002, Docket No.: 0975.1005-022

U.S. Patent Application No. 10/200,795, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed July 22, 2002, Docket No.: 0975.1005-023

U.S. Patent Application No. 10/208,195, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed July 29, 2002, Docket No.: 0975.1005-024

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date

☒ The specification for the above cited co-pending applications is identical to the present specification (09/756,398). Therefore, only a copy of the current claims for each application is enclosed. Copies of the specifications of the co-pending applications will be provided upon request.

☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

☒ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

☐ Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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ATTORNEY DOCKET NO.

0975.1005-006

APPLICATION NO.

09/756,398

INFORMATION DISCLOSURE CITATION  
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September 10, 2002

(See several sheets if necessary)

APPLICANT

Junming Le et al.

FILING DATE

January 8, 2001

GROUP

1642

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## U.S. PATENT DOCUMENTS

TECH CENTER 1600/2900

EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AF	5,223,395	06/29/93	Gero			
	AG	5,436,154	07/25/95	Barbanti et al.			
	AH	5,654,407	08/05/97	Boyle et al.			
	AI	5,700,788	12/23/97	Mongelli et al.			
	AJ	5,730,975	03/24/98	Hotamisligil et al.			
	AK	5,741,488	04/21/98	Feldman et al.			
	AA2	5,776,947	07/07/98	Kroemer et al.			
	AB2	6,015,558	01/18/00	Hotamisligil et al.			
	AC2	6,172,202 B1	01/09/01	Marcucci et al.			
	AD2	6,194,451 B1	02/27/01	Alpegiani et al.			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AL5	0 288 088 B1	26 OCT 88	EPO			
	AM5	0 351 789 B1	24 JAN 90	EPO			
	AN5	0 453 898 A2	30 OCT 91	EPO			X

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR8	Oliff, A., et al., "Tumors Secreting Human TNF/Cachectin Induce Cachexia in Mice," <i>Cell</i> , 50:555-563 (1987).
	AS8	Mule, J.J., et al., "Antitumor Activity of Recombinant Interleukin 6 in Mice," <i>The Journal of Experimental Medicine</i> , 171:629-636 (1990).
	AT8	Luettig, B., et al., "Evidence For The Existence Of Two Forms Of Membrane Tumor Necrosis Factor: An Integral Protein And A Molecule Attached To Its Receptor," <i>The Journal of Immunology</i> , 143:4034-4038 (1989).
	AU8	Barbuto, J.A.M., et al., "Production of neutralizing antibodies to tumor necrosis factor by human tumor-infiltrating B lymphocytes," <i>Proceedings of the American Association for Cancer Research</i> , 34:487, Abstract 2904, (1993).

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PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.  
0975.1005-006APPLICATION NO.  
09/756,198**RECEIVED**INFORMATION DISCLOSURE CITATION  
IN AN APPLICATIONAPPLICANT  
Junming Le et al.

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(See several sheets if necessary)

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## FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
AO5	0 585 705 A1	09 MAR 94	EPO			
AP5	0 614 984 A2	14 SEP 94	EPO			
AQ5	0 663 836 B1	26 JUL 95	EPO			
AL6	WO 89/08460	21 SEP 89	PCT			
AM6	WO 90/01950	08 MAR 90	PCT			
AN6	WO 91/04054	04 APR 91	PCT			
AO6	WO 92/01472	06 FEB 92	PCT			
AP6	WO 93/11236	10 JUN 93	PCT			
AQ6	WO 94/08609	28 APR 94	PCT			
AL7	WO 94/08619	28 APR 94	PCT			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AV8	Bendtzen, K., et al., "Auto-Antibodies To IL-1 $\alpha$ and TNF $\alpha$ In Normal Individuals And In Infectious And Immunoinflammatory Disorders," <i>The Physiological and Pathological Effects of Cytokines</i> , 10B:447-452 (1990).
AW8	Fomsgaard, A., et al., "Auto-Antibodies To Tumour Necrosis Factor $\alpha$ In Healthy Humans And Patients With Inflammatory Diseases And Gram-Negative Bacterial Infections," <i>Scand. J. Immunol.</i> , 30:219-223 (1989).
AX8	James, K. and Bell, G.T., "Human Monoclonal Antibody Production Current Status And Future Prospects," <i>Journal of Immunological Methods</i> , 100:5-40 (1987).
AY8	Alberts, B. et al., <i>Molecular Biology of the Cell</i> , Garland Publishing Inc., pp 182-183 (1983).
AZ8	Simpson, S.Q., et al., "Role Of Tumor Necrosis Factor In Sepsis And Acute Lung Injury," <i>Critical Care Clinics</i> , 5:27-47 (1989).
AR9	Bendtzen, K., et al., "Native inhibitors (autoantibodies) of IL-1 $\alpha$ and TNF," <i>Immunology Today</i> , 10(7):222 (1989).

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ATTORNEY DOCKET NO.  
0975.1005-006APPLICATION NO.  
09/756,388INFORMATION DISCLOSURE CITATION  
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Junming Le et al.

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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AS9	Davenport, C., et al., "Stimulation Of Human B Cells Specific For Candida Albicans For Monoclonal Antibody Production," <i>FEMS Microbiol Immunol</i> , 4(6):335-343 Abstract (1992).
AT9	Pennica, D., et al., "Human tumour necrosis factor: precursor structure, expression and homology to lymphotoxin," <i>Nature</i> , 312(20/27):724-729 (1984).
AU9	Gray, P.W., et al., "Cloning and expression of cDNA for human lymphotoxin, a lymphokine with tumour necrosis activity," <i>Nature</i> , 312(20/27):721-724 (1984).
AV9	Petersen, C.M., et al., "Bioactive human recombinant tumor necrosis factor- $\alpha$ : an unstable dimer?," <i>Eur. J. Immunol.</i> , 19:1887-1894 (1989).
AW9	Smith, C. A., et al., "A Receptor for Tumor Necrosis Factor Defines an Unusual Family of Cellular and Viral Proteins," <i>Science</i> , 248:1019-1023 (1990).
AX9	Brennan, F.M., et al., "Inhibitory Effect Of TNF $\alpha$ Antibodies On Synovial Cell Interleukin-1 Production In Rheumatoid Arthritis," <i>The Lancet</i> , 244-247 (1989).
AY9	Hahn, T., et al., "Use of monoclonal antibodies to a human cytotoxin for its isolation and for examining the self-induction of resistance to this protein," <i>Proc. Natl. Acad. Sci. USA</i> 82:3814-3818 (1985).
AZ9	Grau, G.E., et al., "Tumor Necrosis Factor (Cachectin) as an Essential Mediator in Murine Cerebral Malaria," <i>Science</i> , 237:1210-1212 (1987).
AR10	Barbanti, E., et al., "A high-affinity neutralizing anti-human TNF- $\alpha$ monoclonal antibody that cross-reacts with human TNF- $\beta$ ," <i>Abstracts</i> , March 6th-9th (1991).
AS10	Jones, E.Y., et al., "Structure of tumour necrosis factor," <i>Nature</i> , 338:225-228 (1989).
AT10	Clark, W. R., "Types of Antibody Reactions," In <i>The Experimental Foundations of Modern Immunology</i> , (NY: John Wiley & Sons, Inc.) 4th Ed., pp 143-155 (1991).
AU10	Beutler, B., et al., "Cachectin and tumour necrosis factor as two sides of the same biological coin," <i>Nature</i> , 320:584-588 (1986).
AV10	Folks, T. M., et al., "Tumor Necrosis factor $\alpha$ induces expression of human immunodeficiency virus in a chronically infected T-cell clone," <i>Proc. Natl. Acad. Sci. USA</i> , 86:2365-2358 (1989).
AW10	Hird, V., et al., "Immunotherapy with Monoclonal Antibodies," In <i>Genes and Cancer</i> (John Wiley & Sons, Ltd.) (1990).
AX10	Rhein, R., "Another sepsis drug down-Immunex' TNF receptor," <i>Biotechnology Newswatch</i> , Monday, October 4, 1993, pp. 1,3.
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Sheet 1 of 1

PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 0975.1005-006	APPLICATION NO. 09/756,398
INFORMATION DISCLOSURE CITATION IN AN APPLICATION September 10, 2002 (Use several sheets if necessary)		APPLICANT Junming Le et al.	
		FILING DATE January 8, 2001	GROUP 1642
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
AY10	Boyle, P., et al., "A Novel Monoclonal Human IgM Autoantibody which Binds Recombinant Human and Mouse Tumor Necrosis Factor- $\alpha$ ," <i>Cellular Immunology</i> , 152:556-568 (1993).		
AZ10	Boyle, P., et al., "The B5 Monoclonal Human Autoantibody Binds to Cell Surface TNF $\alpha$ on Human Lymphoid Cells and Cell Lines and Appears to Recognize a Novel Epitope," <i>Cellular Immunology</i> , 152:569-581 (1993).		
AR11	Sheehan, K.C.F., et al., "Generation And Characterization Of Hamster Monoclonal Antibodies That Neutralize Murine Tumor Necrosis Factors," <i>The Journal of Immunology</i> , 142(11):3884-3893 (1989).		
AS11	Jacob, C.O., et al., "Tumour necrosis factor- $\alpha$ in murine autoimmune 'lupus' nephritis," <i>Nature</i> , 331:356-358 (1988).		
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